[Billing Code 4140-01-P]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The invention listed below is owned by an agency of the U.S. Government and is available for licensing to achieve expeditious commercialization of results of federally-funded research and development. Foreign patent applications are filed on selected inventions to extend market coverage for companies and may also be available for licensing.

FOR FURTHER INFORMATION CONTACT: Jenish Patel, PhD, 240-669-2894; jenish.patel@nih.gov. Licensing information and copies of the U.S. patent application listed below may be obtained by communicating with the indicated licensing contact at the Technology Transfer and Intellectual Property Office, National Institute of Allergy and Infectious Diseases, 5601 Fishers Lane, Rockville, MD, 20852; tel. 301-496-2644. A signed Confidential Disclosure Agreement will be required to receive copies of unpublished patent applications.

SUPPLEMENTARY INFORMATION: Technology description follows.

Protein Nanoparticles for Antigen Display in Vaccines

Description of Technology:

The technology relates to a protein-based nanoparticle platform that allows presentation of immunogenic molecules such as influenza virus antigens. This protein platform is made up of hepatitis B capsid/core proteins. The core proteins contain immunogenic loop c/e1, where other antigens can be inserted and the chimeric protein retains the ability to form capsid-like particles. The technology describes the insertion of one or more copies of influenza epitopes derived from the globular head or the stem region of hemagglutinin protein into or around the c/e1 loop of the core protein. The nanoparticles formed by the use of Hepatitis B virus core proteins can be disassembled and re-assembled, allowing mixing of antigens. Furthermore, the nanoparticles can be expressed in prokaryotic and eukaryotic expression systems. Thus, the platform provides a means for an optimal display of influenza epitopes for the induction of immune response including broadly neutralizing antibodies against the virus and therefore has the potential to be developed into an efficient universal vaccine against influenza virus infection.

This technology is available for licensing for commercial development in accordance with 35 U.S.C. 209 and 37 CFR part 404, as well as for further development and evaluation under a research collaboration.

Potential Commercial Applications:

- Vaccine against viruses; vaccines against influenza virus; universal influenza virus vaccine

Competitive Advantages:

- The nanoparticles may be disassembled and re-assembled allowing mixing of antigens
- Expression in prokaryotic and eukaryotic systems

- Avoids production and usage of live viruses for vaccine generation
- Effective immune response due to the use of authentic viral antigens
- Stability of particle and immunogenicity after high temperature exposure
- Incorporation of epitopes from group 1 and group 2 influenza viruses
- Broadly neutralizing antibodies against influenza virus

Development Stage:

- Pre-clinical; in vivo data available (animal)

Inventors: Audray K. Harris, Ph.D., (NIAID) and Dustin McCraw, Ph.D. (NIAID)

Publications: Gallagher JR, et al. Characterization of the disassembly and reassembly of the HBV glycoprotein surface antigen, a pliable nanoparticle vaccine platform. Virology, 2017, Feb; 502:176-187 [PMID 28061386]

Intellectual Property: HHS Reference No. E-005-2017/0 - US Patent Application No. 62/540,474 filed August 2, 2017.

Licensing Contact: Jenish Patel, Ph.D., 240-669-2894; jenish.patel@nih.gov

Collaborative Research Opportunity: The National Institute of Allergy and Infectious Diseases is also seeking statements of capability or interest from parties interested in collaborative research. NIAID would like a prospective collaborator to have one or more of the following capabilities: (1) capacity to produce recombinant protein for animal vaccine studies; (2) perform and evaluate immunogenicity (antibody response) of influenza vaccine antigens in animal (e.g. mouse models); (3) perform and evaluate challenge and protection studies of vaccines and influenza viruses. (e.g. mouse models); and (4) if results are promising from animal studies, capacity to generate clinical grade

materials and perform clinical studies. NIAID will consider executing a Confidentiality Agreement with a prospective collaborator to facilitate receipt of a Capability Statement if requested. For collaboration opportunities, please contact Jenish Patel, PhD, 240-669-2894; jenish.patel@nih.gov.

Dated: February 27, 2018.

Suzanne Frisbie,

Deputy Director,

Technology Transfer and Intellectual Property Office,

National Institute of Allergy and Infectious Diseases.

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